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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,786	10/03/2003	Rachel Meyers	MPI00-317P1RCN1M	8269

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MILLENNIUM PHARMACEUTICALS, INC.
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Cambridge, MA 02139

EXAMINER

STRZELECKA, TERESA E

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/678,786

Applicant(s)

MEYERS ET AL.

Examiner

Teresa E. Strzelecka

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. Prior to setting forth the Restriction Requirement, it is pointed out that applicants have presented claims 1-24 in improper format. The claims are improperly joined as the various groups indicated below appear to encompass distinct inventions (polynucleotides and polypeptides with different sequences, antibodies to polypeptides with different amino acid sequences) to such an extent that they are considered separately patentable. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because these are not proper species.
2. In addition, each Group detailed below reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid or nucleic acid sequences, the Applicants must further elect a single amino acid or a single nucleic acid sequence (See MPEP 803.04).
3. It is noted that the restriction Groups are set forth as Groups I-XXXV for convenience. However, each restriction Group actually comprises the numbers of Groups which read on each patentably distinct nucleic acid, polypeptide or antibody specificity.
4. In addition, it is noted that the claims are drawn to isolated 32374 or 18431 nucleic acid molecule or to isolated 32374 or 18431 polypeptide. In case these numbers denote multiple nucleic acid or polypeptide sequences not identified in the pending claims, further restrictions will apply.
5. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3 and 6, drawn to an isolated nucleic acid molecule, a host cell comprising the nucleic acid and a method for producing a polypeptide using the nucleic acid, classified in class 536, subclass 23.1, for example.
- II. Claim 4, drawn to an isolated polypeptide, classified in class 530, subclass 300, for example.
- III. Claim 5, drawn to an antibody to a polypeptide, classified in class 530, subclass 387.1, for example.
- IV. Claim 7 (in part), drawn to a method for detecting the presence of a nucleic acid molecule in a sample by contacting the sample with a compound that hybridizes to the nucleic acid, classified in class 435, subclass 6, for example.

If Group IV is elected, claim 7 will be examined to the extent that it reads on the nucleic acid.

- V. Claim 7 (in part), drawn to a method for detecting the presence of a polypeptide in a sample by contacting the sample with a compound that hybridizes to the nucleic acid, classified in class 435, subclass 7.1, for example.

If Group V is elected, claim 7 will be examined to the extent that it reads on the polypeptide.

- VI. Claim 8 (in part), drawn to kit comprising a compound which selectively hybridizes to the nucleic acid, classified in class 435, subclass 810, for example.

If Group VI is elected, claim 8 will be examined to the extent that it reads on the nucleic acid.

- VII. Claim 8 (in part), drawn to kit comprising a compound which binds to the polypeptide, classified in class 435, subclass 810, for example.

If Group VII is elected, claim 8 will be examined to the extent that it reads on the polypeptide.

- VIII. Claims 9 and 10, drawn to methods of identifying a compound which binds to the polypeptide or which modulates its activity, classified in class 436, subclass 501, for example.
- IX. Claim 11, drawn to a method of identifying a nucleic acid molecule associated with a disorder by hybridizing the nucleic acid in a sample with a hybridization probe and identifying the nucleic acid molecule associated with a disorder, classified in class 435, subclass 6, for example.
- X. Claim 12, drawn to a method of identifying a nucleic acid molecule associated with a disorder by contacting the nucleic acid in a sample with a pair of amplification primers and identifying the nucleic acid molecule associated with a disorder, classified in class 435, subclass 91.1, for example.
- XI. Claim 13, drawn to a method of identifying a polypeptide associated with a disorder by contacting a sample comprising polypeptides with polypeptide binding partner and identifying the polypeptide associated with a disorder, classified in class 435, subclass 7.8, for example.
- XII. Claim 14, drawn to a method of identifying a subject having a disorder or at risk for developing the disorder by hybridizing the nucleic acid in a sample with a hybridization probe and identifying the subject having a disorder or at risk for developing the disorder, classified in class 435, subclass 6, for example.
- XIII. Claim 15, drawn to a method of identifying a subject having a disorder or at risk for developing the disorder by contacting the nucleic acid in a sample with a pair of

amplification primers and identifying the subject having a disorder or at risk for developing the disorder, classified in class 435, subclass 91.1, for example.

XIV. Claim 16, drawn to a method of identifying a subject having a disorder or at risk for developing the disorder by contacting a sample comprising polypeptides with a polypeptide binding partner and identifying the subject having a disorder or at risk for developing the disorder, classified in class 435, subclass 7.8, for example.

XV. Claim 17 (in part), drawn to a method for identifying a compound capable of treating a disorder characterized by aberrant nucleic acid expression by assaying the ability of the compound to modulate the nucleic acid expression, classified in class 436, subclass 503, for example.

If Group XV is elected, claim 17 will be examined to the extent that it reads on the nucleic acid.

XVI. Claim 17 (in part), drawn to a method for identifying a compound capable of treating a disorder characterized by aberrant polypeptide activity by assaying the ability of the compound to modulate the polypeptide activity, classified in class 436, subclass 512, for example.

If Group XVI is elected, claim 17 will be examined to the extent that it reads on the polypeptide.

XVII. Claims 18 (in part), 23 and 24, drawn to a method for treating a subject having a disorder or at risk of developing a disorder by administering to the subject a modulator of the nucleic acid molecule, classified in class 514, subclass 1, for example.

If Group XVII is elected, claim 18 will be examined to the extent that it reads on the nucleic acid.

XVIII. Claims 18 (in part), 23 and 24, drawn to a method for treating a subject having a disorder or at risk of developing a disorder by administering to the subject a modulator of the polypeptide, classified in class 514, subclass 1, for example.

If Group XVIII is elected, claim 18 will be examined to the extent that it reads on the polypeptide.

XIX. Claims 18 (in part), 19 a), 23 and 24, drawn to a method for treating a subject having a disorder or at risk of developing a disorder by contacting a cell with a 32374 or 18431 modulator, where the modulator is a small molecule, classified in class 514, subclass 1, for example.

If Group XIX is elected, claim 18 will be examined to the extent that it reads on the cell.

XX. Claims 18 (in part), 19 b), 23 and 24, drawn to a method for treating a subject having a disorder or at risk of developing a disorder by contacting a cell with a 32374 or 18431 modulator, where the modulator is a peptide, classified in class 424, subclass 184.1, for example.

If Group XX is elected, claim 18 will be examined to the extent that it reads on the cell.

XXI. Claims 18 (in part), 19 c), 23 and 24, drawn to a method for treating a subject having a disorder or at risk of developing a disorder by contacting a cell with a 32374 or 18431 modulator, where the modulator is a phosphopeptide, classified in class 530, subclass 300, for example.

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If Group XXI is elected, claim 18 will be examined to the extent that it reads on the cell.

XXII. Claims 18 (in part), 19 d), 23 and 24, drawn to a method for treating a subject having a disorder or at risk of developing a disorder by contacting a cell with a 32374 or 18431 modulator, where the modulator is an anti-32374 or 18431 antibody, classified in class 424, subclass 130.1, for example.

If Group XXII is elected, claim 18 will be examined to the extent that it reads on the cell.

XXIII. Claims 18 (in part), 19 e), 23 and 24, drawn to a method for treating a subject having a disorder or at risk of developing a disorder by contacting a cell with a 32374 or 18431 modulator, where the modulator is a 32374 or 18431 polypeptide, classified in class 530, subclass 350, for example.

If Group XXIII is elected, claim 18 will be examined to the extent that it reads on the cell.

XXIV. Claims 18 (in part), 19 f), 23 and 24, drawn to a method for treating a subject having a disorder or at risk of developing a disorder by contacting a cell with a 32374 or 18431 modulator, where the modulator is a 32374 or 18431 polypeptide with at least 90% sequence identity to SEQ ID NO: 2 or SEQ ID NO: 5, classified in class 424, subclass 185.1, for example.

If Group XXIV is elected, claim 18 will be examined to the extent that it reads on the cell.

XXV. Claims 18 (in part), 19 g), 23 and 24, drawn to a method for treating a subject having a disorder or at risk of developing a disorder by contacting a cell with a 32374 or

18431 modulator, where the modulator is a naturally occurring allelic variant of a polypeptide consisting of the amino acid sequence of SEQ ID NO: 2 or SEQ ID NO: 5, encoded by a nucleic acid molecule which hybridizes to a complement of a nucleic acid molecule consisting of SEQ ID NO: 1 or SEQ ID NO: 4, classified in class 530, subclass 350, for example.

If Group XXV is elected, claim 18 will be examined to the extent that it reads on the cell.

XXVI. Claims 18 (in part), 20 a), 23 and 24, drawn to a method for treating a subject having a disorder or at risk of developing a disorder by contacting a cell with a 32374 or 18431 modulator, where the modulator is an antisense nucleic acid molecule, classified in class 536, subclass 24.5, for example.

If Group XXVI is elected, claim 18 will be examined to the extent that it reads on the cell.

XXVII. Claims 18 (in part), 20 b), 23 and 24, drawn to a method for treating a subject having a disorder or at risk of developing a disorder by contacting a cell with a 32374 or 18431 modulator, where the modulator is a ribozyme, classified in class 514, subclass 44, for example.

If Group XXVII is elected, claim 18 will be examined to the extent that it reads on the cell.

XXVIII. Claims 18 (in part), 20 c), 23 and 24, drawn to a method for treating a subject having a disorder or at risk of developing a disorder by contacting a cell with a 32374 or 18431 modulator, where the modulator is the nucleotide sequence of SEQ ID NO: 1 or SEQ ID NO: 4, classified in class 514, subclass 44, for example.

If Group XXVIII is elected, claim 18 will be examined to the extent that it reads on the cell.

XXIX. Claims 18 (in part), 20 d), 23 and 24, drawn to a method for treating a subject having a disorder or at risk of developing a disorder by contacting a cell with a 32374 or 18431 modulator, where the modulator is the nucleotide sequence encoding a polypeptide with at least 90% sequence identity to SEQ ID NO: 2 or SEQ ID NO: 5, classified in class 514, subclass 44, for example.

If Group XXIX is elected, claim 18 will be examined to the extent that it reads on the cell.

XXX. Claims 18 (in part), 20 e), 23 and 24, drawn to a method for treating a subject having a disorder or at risk of developing a disorder by contacting a cell with a 32374 or 18431 modulator, where the modulator is the nucleotide sequence encoding a naturally occurring allelic variant of a polypeptide consisting of the amino acid sequence of SEQ ID NO: 2 or SEQ ID NO: 5, which hybridizes to a complement of a nucleic acid molecule consisting of SEQ ID NO: 1 or SEQ ID NO: 4, classified in class 514, subclass 44, for example.

If Group XXX is elected, claim 18 will be examined to the extent that it reads on the cell.

XXXI. Claims 18 (in part), 20 e), 23 and 24, drawn to a method for treating a subject having a disorder or at risk of developing a disorder by contacting a cell with a 32374 or 18431 modulator, where the modulator is a gene therapy vector, classified in class 424, subclass 93.1, for example.

If Group XXXI is elected, claim 18 will be examined to the extent that it reads on the cell.

XXXII. Claim 21 (in part), drawn to a method for evaluating the efficacy of a treatment of a disorder, by treating a subject with a protocol under evaluation and assessing the expression level of a 32374 or 18431 nucleic acid, classified in class 435, subclass 91.2, for example.

If Group XXXII is elected, claim 21 will be examined to the extent that it reads on the nucleic acid.

XXXIII. Claim 21 (in part), drawn to a method for evaluating the efficacy of a treatment of a disorder, by treating a subject with a protocol under evaluation and assessing the expression level of a 32374 or 18431 polypeptide, classified in class 435, subclass 7.1, for example.

If Group XXXIII is elected, claim 21 will be examined to the extent that it reads on the polypeptide.

XXXIV. Claim 22 (in part), drawn to a method of diagnosing a disorder in a subject, comprising evaluating expression or activity of a 32374 or 18431 nucleic acid molecule, classified in class 435, subclass 6, for example.

If Group XXXIV is elected, claim 22 will be examined to the extent that it reads on the nucleic acid.

XXXV. Claim 22 (in part), drawn to a method of diagnosing a disorder in a subject, comprising evaluating expression or activity of a 32374 or 18431 polypeptide encoded by the 32374 or 18431 nucleic acid molecule, classified in class 435, subclass 7.1, for example.

If Group XXXV is elected, claim 22 will be examined to the extent that it reads on the polypeptide.

6. Claim 18 links inventions XVII-XXXI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim, claim 18. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

7. Inventions I and II are separate and distinct because the inventions are directed to different chemical types regarding the critical limitations therein. For Group II the critical feature is a polypeptide whereas for Group I the critical feature is a polynucleotide. It is acknowledged that various processing steps may cause a polypeptide of Group II to be directed as to its synthesis by a polynucleotide of Group I, however, the completely separate chemical types of the inventions of Groups I and II supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examiner together, as

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compared to being searched separately. Also, it is pointed out that processing that may connect two groups does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

8. Inventions I and III are separate and distinct, as the claims of Invention I are drawn to polynucleotides, while the claims of Group III are drawn to an antibody. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention III would require searching in areas unrelated to polynucleotides, and as such, would require an undue burden on the examiner if not restricted.

9. Inventions I and (VI and VII) are separate and distinct, as the claims of Invention I are drawn to polynucleotides, while the claims of Groups (VI and VII) are drawn to kits comprising compounds which bind to nucleic acids or polypeptides. These are differing biochemical entities having differing biochemical properties, structures and effects. Inventions VI and VII would require searching in areas unrelated to polynucleotides, and as such, would require an undue burden on the examiner if not restricted.

10. Inventions I and (IV, IX, X, XII, XIII, XV, XVII, XXVIII, XXIX, XXX, XXXII, XXXIV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of Group I could be used for an entirely different purpose such as in making the polypeptide of Group II, rather than in the methods of Groups IV, IX, X, XII, XIII, XV, XVII, XXVIII, XXIX, XXX, XXXII, XXXIV.

11. Inventions I and (V, VIII, XI, XIV, XVI, XVIII-XXVII, XXXI, XXXIII, XXXV) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the polynucleotide of Group I is not required for the methods of Groups V, VIII, XI, XIV, XVI, XVIII-XXVII, XXXI, XXXIII, XXXV.

12. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II could be used for an entirely different purpose such as in the method of Group V, rather than for the production of antibodies of Group III.

13. Inventions II and (VI and VII) are separate and distinct, as the claims of Invention II are drawn to polypeptides, while the claims of Groups (VI and VII) are drawn to kits comprising compounds which bind to nucleic acids or polypeptides. These are differing biochemical entities having differing biochemical properties, structures and effects. Inventions VI and VII would require searching in areas unrelated to polypeptides, and as such, would require an undue burden on the examiner if not restricted.

14. Inventions II and (IV, IX, X, XII, XIII, XV, XVII, XIX-XXII, XXVI-XXXII, XXXIV) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are

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not required one for the other in that the polypeptide of Group II is not required for the methods of Groups IV, IX, X, XII, XIII, XV, XVII, XIX-XXII, XXVI-XXXII, XXXIV.

15. Inventions II and (V, VIII, XI, XIV, XVI, XVIII, XXIII-XXV, XXXIII, XXXV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II could be used for an entirely different purpose such as in production of antibodies of Group III, rather than in the methods of Groups V, VIII, XI, XIV, XVI, XVIII, XXIII-XXV, XXXIII, XXXV.

16. Inventions III and (VI and VII) are separate and distinct, as the claims of Invention III are drawn to antibodies, while the claims of Groups (VI and VII) are drawn to kits comprising compounds which bind to nucleic acids or polypeptides. These are differing biochemical entities having differing biochemical properties, structures and effects. Inventions VI and VII would require searching in areas unrelated to antibodies, and as such, would require an undue burden on the examiner if not restricted.

17. Inventions III and (IV, V, VIII-XXI, XXIII-XXXV) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the antibody of Group III is not required for the methods of Groups IV, V, VIII-XXI, XXIII-XXXV.

18. Inventions III and XXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group III could be used for an entirely different purpose such as in detecting the antigen-presenting cells, rather than in the methods of Group XXII.

19. Inventions (IV, V, VIII-XXXV) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to methods which have different method steps, starting materials and goals.

20. Inventions VI and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compound of Group VI which selectively hybridizes to the nucleic acid could be used for an entirely different purpose such as in the isolation of the nucleic acid, rather than in the method of Group IV.

21. Inventions VII and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compound of Group VII which binds to the polypeptide could be used for an

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entirely different purpose such as in the isolation of the nucleic acid, rather than in the method of Group V.

22. Inventions (VI, VII) and VIII-XXXV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the specific binding compounds of Groups VI and VII are not required for the methods of Groups VIII-XXXV.

23. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

24. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected

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product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

25. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

26. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TERESA STRZELECKA
PATENT EXAMINER

Teresa Strzelecka
3/17/06